

REMARKS

The present Amendment in Response to Non-Final Office Action (“response”) responds to a non-final Office Action mailed April 18, 2005 (“Office Action”). The Office Action sets a three month shortened statutory period for response. Filed with the present response is a Petition for Extension of Time Under 37 C.F.R. § 1.136(a) requesting a three month extension of time. Accordingly, a response is timely filed by October 18, 2005.

Status of the Claims and Support for Claim Changes

Claims 1 – 12 are pending; claims 13 – 16 are withdrawn from further consideration. Claims 1 and 2 are presently amended. Support for the current amendments to claims 1 and 2 may be found in Examples 1 and 2 in the instant specification. The negative limitation to “methicillin” is based upon the original disclosure at paragraph [0011]. *See* M.P.E.P. § 2173.05(i) (“If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.”); *see also In re Johnson*, 558 F.2d 1008, 1019, 194 U.S.P.Q. 187, 196 (C.C.P.A. 1977).

Specification

Applicants have amended page 12, paragraph [0028] in the specification to state strain identifiers. Applicants have amended page 11, section 0025 in the specification to capitalize the trademark “CHROMagar™,” and to accompany the trademark by the generic terminology, as requested by the Examiner. Applicants accordingly request the objections to the specification be withdrawn.

Claim Rejections – 35 USC §112

Claims 1 – 12 were rejected under 35 U.S.C. § 112, ¶2 for omitting essential steps. Claim 1 is currently amended to recite observing that resistant microorganisms exhibit growth and non-resistant microorganisms do not exhibit growth; claims 2 – 12 depend upon claim 1. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC §102

Claims 1 and 10 – 11 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication 2002-0076742 A1. Applicants traverse the rejection. Certain limitations of unrejected claim 2 have been incorporated into claim 1. Accordingly, withdrawal of the rejection is requested.

Claims 1 – 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Merlino *et al.* *J. Clin. Microbiol.* 38: 2378-80 (2000) (“Merlino *et al.*”). Applicants traverse. Merlino *et al.* uses oxacillin and methicillin in their agar screening plates. The use of oxacillin and methicillin is not within the scope of claims 1 – 6. Accordingly, Merlino *et al.* does not anticipate claims 1 – 6, and withdrawal of the rejection is requested.

Claim Rejections – 35 USC §103

Claims 1 – 12 are rejected under 35 USC §103(a) as being unpatentable over Merlino in view of Felten *et al.*, *J. Clin. Microbiol.* 40: 2766-71 (2002) (“Felten *et al.*”). Applicants traverse.

At page 7 of the Office Action, the Examiner characterizes the teachings of Merlino *et al.* and admits that “Merlino *et al.* does not teach cephalosporins such as cefoxitin.” The Examiner alleges that “Felten *et al.* teaches a method of detecting methicillin-resistant *Staphylococcus aureus* (MRSA) using cefoxitin.” The Examiner alleges that it would have been obvious “to substitute the methicillin as taught by Merlino *et al.* with the cefoxitin of Felten *et al.* in the method of detecting MRSA because Felten *et al.* teach that cefoxitin is more sensitive and specific for detection of MRSA (page 2769).”

A proper *prima facie* case of obviousness requires *teachings from the prior art* that would have motivated one of ordinary skill to make the proposed combination and would have led one of ordinary skill to have a reasonable expectation of success in substituting methicillin with cefoxitin in an MRSA assay using a chromogenic plate medium. See *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); *In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002) (“[the] factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.”). The Examiner does not provide such a teaching from the prior art, but instead infers that cefoxitin is more sensitive and specific for detection of MRSA than methicillin based on results obtained in separate assay systems. In particular, the Examiner

provides no evidence on the record that would have motivated the proposed modification or would have caused the artisan reasonably to expect that cefoxitin would have worked as well as methicillin in an MRSA assay using a chromogenic plate medium. Without proper motivation or a reasonable expectation of success in the substitution *provided by the prior art*, the Examiner cannot make a proper *prima facie* case of obviousness, and the rejection should be withdrawn.

The state of the art at the time of the invention in fact would have led the artisan of ordinary skill to doubt that cefoxitin would have given results equivalent to methicillin in an MRSA assay using a chromogenic plate medium. Merlino demonstrates that an MRSA assay using oxacillin and methicillin incorporated into a chromogenic medium was unable to detect 70 of 100 community acquired MRSA strains. Merlino at 2380, col. 1. Merlino admits:

The cause of these organisms' growth anomaly on the test chromogenic medium remains unclear but may reflect active co-transportation of methicillin intracellularly with the chromogenic moiety.

Id. at 2380, col. 1. Merlino concludes that "further evaluation of this new chromogenic medium . . . is needed. . . ." *Id.* at 2380, col. 2 (emphasis added). Merlino's uncertainty undermines the allegation that the combination of Merlin and Felten would have given the artisan of ordinary skill a reasonable expectation that methicillin could have been substituted successfully with cefoxitin. To the contrary, Felten states that "cefoxitin induced production of PBP2a [*i.e.*, penicillin-binding protein 2a] *in vitro* in MSSA [*i.e.*, methicillin-susceptible *S. aureus*] isolates," which would have led the artisan of ordinary skill to be concerned that cefoxitin would cause methicillin susceptible strains to appear resistant, resulting in false positives. Felten at 2767, col. 1. Again, without a proper motivation or a reasonable expectation of success in the substitution *provided by the prior art*, the Examiner cannot make a proper *prima facie* case of obviousness, and the rejection should be withdrawn.

CONCLUSION

In view of the above response and amendment, applicants believe the pending application is in condition for allowance.

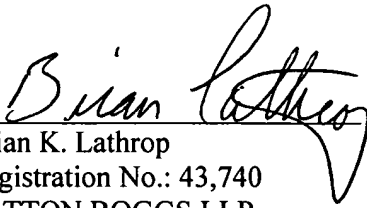
Application No. 10/753,417
Amendment dated October 18, 2005
Reply to Office Action of April 18, 2005

Docket No.: 020187.0173PTUS

Applicants believe the fees provided with this response are sufficient; however, if an additional fee is due, please charge our Deposit Account No. 50-2228, under Order No. 020187.0173PTUS from which the undersigned is authorized to draw.

Dated: October 18, 2005

Respectfully submitted,

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